Testimony
Before the
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

"Continuing Ethics and Management Concerns at the National Institutes of Health and the Public Health Service Commissioned Corps"

Statement of
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Chairman Whitfield, Ranking Member Stupak and Members of the Subcommittee. I am Dr. Raynard Kington, Principal Deputy Director of the National Institutes of Health (NIH). I appear today at your request to testify about the enforcement of the Agency's ethics rules.

NIH's mission is to conduct research that will lead to better methods of diagnosing, treating, preventing, and curing disease. The research that we support has resulted in improvements in detecting disease, better therapies, and more effective vaccines.

The United States leads the world in biomedical research. We have achieved and maintained our preeminent status by balancing a massive public and private sector partnership. The programs of NIH are supported by appropriated funds, whereas the pharmaceutical and biotechnology industries finance their research from revenues or the promise of profits. Nevertheless, the translation of research from the bench to the bedside cannot occur without collaborations between publicly-supported researchers and industry scientists. While some work in government and others operate in industry facilities, they undergo similar training, and their methods are often indistinguishable.

Most biomedical research, whether funded by the public or private sector, is conducted at non-government facilities. An exception to that is the NIH intramural program, where research is conducted in federal facilities by government scientists, although this intramural research represents only ten percent of NIH's overall budget.

It is expected that those at NIH entrusted with Federal funds are faithful stewards of the public trust. This clearly means that NIH-funded research must be free of bias and the influence of profit incentives. To this end, NIH and the Department of Health and Human Services (HHS), working with the Office of Government Ethics, banned any paid-consulting for NIH employees with the pharmaceutical and biotechnology industries.

We took this action because even the suggestion of ethical lapses, apparent or real, in NIH programs would undermine public confidence in federally-supported medical research. We could not allow this to happen.

In addition to these ethics reforms, we disciplined 34 NIH intramural scientists who had violated the previous ethics rules by failing to seek approval for -- or even report -- consulting relationships with industry, by failing to take annual leave while consulting, or by consulting in areas that overlapped with their official duties. These actions were taken because information provided through the Subcommittee's earlier investigation had identified NIH scientists who consulted for industry but had not reported their consulting relationships to NIH. NIH investigated these individuals, as well as other individuals whose cases were discovered when we asked our scientists to report any undisclosed consulting to their supervisors. When violations were found, NIH implemented sanctions ranging from oral admonishments to letters of reprimand to suspensions. In all cases where individual scientists failed to take leave to conduct outside activities, they were directed to pay back that leave to the government. In many cases, scientists returned honoraria that were inappropriately received.

The review of these cases involved multiple components of NIH. The Office of Management Assessment (OMA), NIH's official liaison to the HHS Office of the Inspector General (OIG), conducted reviews of all the cases, determining the facts and identifying violations of rules. My office convened an expert panel of NIH Institute Directors, whose Institutes did not have any cases, to determine whether the scientists' outside activities overlapped with official duties. The NIH ethics office gave technical advice and administrative support to this panel. Ten cases were referred to the OIG due to potential violations of criminal law. Upon completion of the reviews, the Office of Human Resources used existing policies to identify appropriate penalties for those found in violation of the rules.

Two of the cases identified in the internal review are still active. They involve NIH scientists who are also members of the Public Health Service Commissioned Corps (Corps). In each of the cases, NIH concluded that the facts were sufficiently egregious to warrant referral to the Corps, which has independent authority to investigate the facts and the latitude to determine the most appropriate level of discipline for its commissioned officers through the Board of Inquiry process.

We also continue to address issues raised in the course of the Committee's investigation of the particular cases under discussion today. First, as NIH witnesses testified at this Subcommittee's June 14, 2006, hearing, we are in the process of clarifying guidelines for NIH investigators to inform them which formal mechanisms are to be used to transfer human tissue samples to outside collaborators. In cases involving the transfer of material derived from human subjects, all written agreements must be accompanied by rigorous checks and balances, including the review and approval by senior leadership at the relevant Institute. Second, the use of samples or data of human subjects, as HHS regulations prescribe, is overseen by an Institutional Review Board or by the NIH Office of Human Subjects of Research. Third, NIH is clarifying its policies regarding the presentation of scientific information to Advisory Committees at the Food and Drug Administration (FDA). NIH scientists may not appear at FDA Advisory Committee meetings as representatives of outside companies. There may, however, be circumstances where it would be both appropriate and beneficial for a particular NIH scientist to appear at an FDA Advisory Committee meeting as part of his or her official duties. NIH is preparing a specific policy which will describe the circumstances in which such appearances are permissible. We will keep the Subcommittee apprised of our progress as we implement these changes.

As a result of these investigations and reforms implemented by NIH, cases such as those being discussed today are hopefully remnants of past policies. With new restrictions in place and a more efficient and rigorous ethics program underway, we are confident that the problems previously identified by this Subcommittee are behind us.

Thank you for the opportunity to testify. I will be pleased to answer any questions Members of the Subcommittee may have.